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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,280	09/27/2005	**Hirofumi Yazaki**	1027550-000160	1581

21839 7590 08/19/2010

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EXAMINER	
LLOYD, EMILY M	

ART UNIT	PAPER NUMBER
3736	

NOTIFICATION DATE	DELIVERY MODE
08/19/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/551,280	YAZAKI ET AL.	
	Examiner	Art Unit	
	EMILY M. LLOYD	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 January 2010 and 06 May 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5-7,9-11,13,14,16 and 19-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-7,9-11,13,14,16 and 19-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to Applicant's 13 January and 6 May 2010 amendments. The Examiner acknowledges Applicant's amendments to claims 1, 2, 5, 7, 9, 13, 14 and 19, the addition of claims 20-24, and the cancellation of claims 3, 4, 8, 12, 15, 17 and 18. Currently, claims 1, 2, 5-7, 9-11, 13, 14, 16 and 19-24 are pending.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2 and 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by United States Patent 3734095 (Santomieri).

Regarding claim 1, Santomieri discloses a humor sampling implement (Figures 1-3, 6 and 7) comprising: a main frame part having a humor transfer channel (needle 86 Figures 2, 3, 6 and 7) provided to collect humor through a humor inflow port (distal end of needle 86) and transfer said humor to a humor outflow port (opening 112 Figure 6); and, a detection part provided at said main frame part to detect a predetermined component of said humor transferred through said humor transfer channel (chamber 110 provides for determining if blood is present to indicate "a successful venipuncture" (Column 5 lines 13-16); wherein said main frame part is provided with a convex part

(nub 122 Figure 7) arranged so as to be in overlapped relationship with said detection part in plan view (chamber 110 is above nub 122 such that they are overlapping in a plan view) and protruding in said humor transfer channel toward said humor outflow port (nub 122 points upwards toward opening 112); and said humor transfer channel comprises a first humor transfer channel that opens to said humor inflow port (distal end of needle 86), and a second humor transfer channel connected to said first humor transfer channel (portion of needle 86 proximal to/above nub 122 Figure 7), said second humor transfer channel being different from said first humor transfer channel in a direction of humor transfer in which said humor is transferred along the humor transfer channel (Figure 7); and said convex part is provided at an end portion on a humor outflow port side of said first humor transfer channel of said main frame part so as to protrude in said second humor transfer channel (Figure 7); and wherein the direction of humor transfer in said first humor transfer channel and the direction of humor transfer in said second humor transfer channel are substantially orthogonal to each other (Figure 7).

Regarding claim 2, Santomieri discloses that the convex part is arranged so as to be in overlapped relationship with substantially a center of said detection part in plan view (chamber 110 is above nub 122 such that they are overlapping in a plan view, further, the nub is aligned with the center longitudinally, which is a center of the detection part).

Regarding claims 9-11, Santomieri discloses a method of humor sampling, comprising: collecting humor (Column 5 lines 13-16) through a humor inflow port (distel

end of needle 86) of a main frame part of a humor sampling implement (Figures 1-3, 6 and 7); and introducing the humor collected at the humor inflow port to a humor transfer channel (body of needle 86) and transferring the humor along the humor transfer channel to a humor outflow port (opening 112 Figure 6); the main frame part comprising a projection protruding in said humor transfer channel toward said humor outflow port (nub 122 Figure 7 is upward towards opening 112); wherein the transfer of the humor along the humor transfer channel comprises transferring the humor collected at the humor inflow port along a first humor transfer channel which opens to said humor inflow port (portion of needle 86 between its distal end and nub 122) and transferring the humor along a second humor transfer channel which is connected to said first humor transfer channel and which is orthogonally oriented relative to the first humor transfer channel (portion of needle 86 proximal/above nub 122 Figure 7).

Claim 14 is rejected under 35 U.S.C. 102(b) as being anticipated by US 6083460 (Morikawa et al.).

Regarding claim 14, Morikawa et al. disclose a humor sampling implement comprising: a main frame part (52 see especially Figure 3, see also entire document) provided with a humor inflow port (523), a humor outflow port (527 as well as 526 and 55; one of ordinary skill in the art could also interpret the area below 53 as an outflow port) and a humor transfer channel (520) extending between the humor inflow port and the humor outflow port; the main frame comprising a projection provided along said humor transfer channel (the curves of 52 between 54 and 55 and pointing towards 532)

to at least prevent an increase in a cross-sectional area of a portion of the humor transfer channel between the projection and the humor outflow port (the cross-section of 54 narrows as it approaches this curve); and a test paper (53) provided at said main frame to absorb at least some of the humor supplied to the humor outflow port and detect a component in the humor (test paper 53 is for absorbing humor and detecting a component in the humor, see entire document); wherein the projection possess a configuration such that a cross-sectional area of the projection decreases toward the humor outlet port (the cross-section of the curves of 52 between 54 and 55 and pointing towards 532 decrease in a direction towards 53 and 532); wherein the humor transfer channel comprises a first humor transfer channel (520) opening to the humor inflow port (523) and a second humor transfer channel connected to the first humor transfer channel (54; could also be 55), the second humor transfer channel being oriented at an angle other than zero degrees relative to the first humor transfer channel (Figure 3).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Santomieri.

Regarding claim 5, Santomieri does not disclose expressly that V1/V2 is in a range of from 0.04 to 0.7, where V1 is a volume of said convex part, and V2 is an inside volume of said second humor transfer channel. Instead, Santomieri is mute as to the volumes of these components.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to provide the claimed volume ratio because Applicant has not disclosed that the volume ratio provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the

art, furthermore, would have expected Santomieri's device, and applicant's invention, to perform equally well with either the setup taught by Santomieri or the claimed volume ratio because both devices would perform the same function of collecting a body fluid equally well.

Therefore, it would have been prima facie obvious to modify Santomieri to obtain the invention as specified in claim 5 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Santomieri.

Regarding claim 6, Santomieri discloses the humor sampling implement as set forth in claim 1. Santomieri does not expressly disclose that said main frame part has a lower member, and an upper member which is positioned on said lower member and which, together with said lower member, defines a part of said humor transfer channel. However, the Examiner notes that it is obvious to make parts/components separable (MPEP 2144.04 V C Making Separable) which could provide, for example, easier and more cost effective manufacturing of the main frame. Additionally, the Examiner notes that it is well known in the art of fluid sampling to assemble a main frame part with an upper and lower member to form a channel.

Regarding claim 7, Santomieri teaches the limitations as described above with respect to claims 1, 2, 5 and 6.

Claims 16 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morikawa et al.

Regarding claim 19, Morikawa et al. disclose the humor sampling implements as set forth in claim 14. Morikawa et al. do not disclose expressly that V1/V2 is in a range of from 0.04 to 0.7, where V1 is a volume of said convex part, and V2 is an inside volume of said second humor transfer channel. Instead, Morikawa et al. are mute as to the volumes of these components.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to provide the claimed volume ratio because Applicant has not disclosed that the volume ratio provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Morikawa et al.'s device, and applicant's invention, to perform equally well with either the setup taught by Morikawa et al. or the claimed volume ratio because both devices would perform the same function of collecting a body fluid equally well.

Therefore, it would have been prima facie obvious to modify Morikawa et al. to obtain the invention as specified in claim 19 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Morikawa et al.

Regarding claim 16, Morikawa et al. disclose the humor sampling implements as set forth in claim 14. Morikawa et al. do not expressly disclose that said main frame part has a lower member, and an upper member which is positioned on said lower member and which, together with said lower member, defines a part of said humor transfer channel. However, the Examiner notes that it is obvious to make

parts/components separable (MPEP 2144.04 V C Making Separable) which could provide, for example, easier and more cost effective manufacturing of the main frame. Additionally, the Examiner notes that it is well known in the art of fluid sampling to assemble a main frame part with an upper and lower member to form a channel.

Response to Arguments

Applicant's arguments filed 13 January and 6 May 2010 have been fully considered but they are not persuasive.

Regarding Applicant's argument that the portions of Santomieri identified as the first and second humor transfer channels are not orthogonal, the Examiner disagrees. The Examiner notes that a bottom portion/first channel is horizontal and a top portion/second channel is vertical, such that together they are orthogonal.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the convex part functions such that blood transferred in the first blood transfer channel fills sufficiently the space at the boundary between the first and second blood transfer channels) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Regarding Applicant's argument that the curve of Morikawa does not provide a decrease in cross-sectional area towards a humor outlet port, the Examiner disagrees. The Examiner notes that the full size version of the figure in the patent shows a

narrowing at the curve circled by the Applicant. Thus, depending on the interpretation of the humor outlet port, there is a narrowing in cross-section towards the humor outlet port.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EMILY M. LLOYD whose telephone number is (571)272-2951. The examiner can normally be reached on Monday through Friday 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Emily M Lloyd
Examiner
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